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Doran R. Pace, Patent Attorney

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322
Docket No. UF-152FWCD2
Patent No. 7,311,921

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Janet K. Yamamoto
Issued	:	December 25, 2007
Patent No.	:	7,311,921
For	:	Multi-Subtype FIV Vaccines

Mail Stop Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below is the column and line number where errors occurred in the patent. In the right-hand column is the page and line number in the application where the correct information appears.

Patent Reads:	**Application Reads:**
Column 4, line 58:	Page 7, line 5:
"FIV_{DiX}"	--FIV_{Dix}--

Column 14, line 7:	Page 19, line 24:
"FIV_{pet} Overall"	--FIV_{pet}. Overall--
Column 19, table 8, line 2:	Page 28, table 8, line 2:
"10^4 10^4 10^4 ND"	--10^4 10^4 10^1 ND--

A true and correct copy of pages 17, 13, 19 and 28 of the specification, as filed which support Applicants' assertion of the errors on the part of the Patent Office, accompany this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,

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DRP/dc/trt
Attachments: Copy of pages 7, 13, 19 and 28 of the specification; Official Certificate of Correction

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,311,921

APPLICATION NO.: 10/636,079

DATED : December 25, 2007

INVENTOR : Janet K. Yamamoto

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4,
Line 58, "FIV_{DiX}" should read --FIV_{Dix}--.

Column 14,
Line 7, "FIV_{pet} Overall" should read --FIV_{pet}. Overall--.

Column 19,
Table 8, Line 2, "10^4 10^4 10^4 ND" should read --10^4 10^4 10^1 ND--.

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well as for propagating and producing FIV viral strains *in vitro*. Both the IL-2-dependent FeT-1C and IL-2-independent FeT-J uninfected cell lines were tested over 20 times for reverse transcriptase (RT) activity in culture fluids and for FIV proviral sequence by PCR and were confirmed negative for FIV. FeT-J cell line was highly infectable with all of the FIV strains tested, including FIV_{Shi}, FIV_{Dix}, FIV_{UK8}, FIV_{Pet} and FIV_{Bang} but was more difficult to directly infect with FIV_{Shi}.

The subject invention further concerns cellular products produced by the cell lines of the present invention. The cellular products can be isolated and detected using procedures known to the skilled artisan. Antibodies to the cell lines can also be produced using known methods and are contemplated by the subject invention.

The FIV uninfected cell lines designated as FeT-1C (ATCC Accession No. CRL 11968) and as FeT-J (ATCC Accession No. CRL 11967) were both deposited with the American Type Culture Collection, Rockville, Maryland on August 24, 1995. FIV_{Bang}- (ATCC Accession No. 11975) and FIV_{Shi}- (ATCC Accession No. 11976) infected cell lines were deposited with the American Type Culture Collection on August 25, 1995.

The subject cultures have been deposited under conditions that assure that access to the culture will be available during the pendency of this patent application to one determined by the Commissioner of Patents and Trademarks to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122. The deposit will be available as required by foreign patent laws in countries wherein counterparts of the subject application, or its progeny, are filed. However, it should be understood that the availability of a deposit does not constitute a license to practice the subject invention in derogation of patent rights granted by governmental action.

Further, the subject culture deposit will be stored and made available to the public in accord with the provisions of the Budapest Treaty for the Deposit of Microorganisms, i.e., it will be stored with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposit, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of any patent which may issue disclosing the culture. The depositor

chromatography and confirmed by amino acid sequence analysis performed on the peak sample.

The peptide coated plates were washed once with Buffer 3 immediately prior to use. The serum samples were diluted at 1:200 in Buffer 3 and incubated in the FIV antigen coated wells for 1 hr at 37° C, then washed 6 times. The wells were washed with wash solution, incubated with biotinylated anti-cat IgG (Vector Laboratories, Burlingame, CA) for 1 hr at 37°C, washed 6-times, and incubated with horseradish peroxidase conjugated Streptavidin (Vector Laboratories) for 1 hr at 37°C. The wells were then washed 6 times with wash solution and incubated with ELISA substrate solution (0.005% tetramethylbenzidine and 0.015% H_2O_2 in 0.96-% citrate solution) at room temperature. The reaction was stopped with 0.1 M hydrofluoric acid upon establishment of visible reaction color in the sequentially diluted standards consisting of known FIV-positive cat serum. Light absorption was measured with a BioRad ELISA reader (Bio-Rad Laboratories, Hercules, CA) at optical density of 414 nm.

Polymerase Chain Reaction (PCR). The proviral DNA levels of infected cells were monitored by differential PCR, which was recently developed to distinguish multiple FIV strains from the same or different subtypes (Okada *et al.*, 1994). As a means of increasing the sensitivity of PCR, the nested PCR primer sets shown in Table 1 were used. PCR was performed in a two stage reaction, first with a pair of outer primers (common for all FIV strains) under conditions as described in Okada *et al.*, 1994. In the second PCR stage, 1/25 of the first stage product was amplified using the inner primers (specific for each FIV strain). Using nested PCR, cells infected with FIV_{Pet}, FIV_{UK8}, FIV_{Bang}, FIV_{Aom1}, FIV_{Aom2} and FIV_{Shi} can be distinguished from each other.

infection against homologous FIV_{Shi} challenge as well as against heterologous FIV_{Bang} challenge.

The dual-subtype vaccinated cats (Pet/FL-4 cells and Shi/FeT-1C cells) developed FIV antibodies specific for the viral core protein p25 (also call FIV p28) after the second immunization (Figure 2). Higher antibody titers to other viral antigens were demonstrated after the third to fourth immunization. VN antibodies to FIV_{Pet} developed after the second immunization, whereas VN antibodies to FIV_{Shi} developed after the fourth immunization (Table 4). CTL responses to FIV_{Pet} and FIV_{Shi} were detected as early as the third immunization in all cats tested (Table 3) and stronger CTL responses to both strains were developed after the fourth immunization. Further, two of the three cats tested developed CTL responses to FIV_{Bang} after the fourth immunization. Results indicate that after 4 vaccinations, the dual-subtype vaccine induced strong CTL responses to FIV_{Pet} and FIV_{Shi} (Table 3) and high FIV antibodies, including VN antibody titers, to both FIV strains (Table 4).

The cats immunized with inactivated Shi/FeT-1C cells developed FIV antibodies specific for the viral core protein p25 after the second immunization and antibodies to other viral antigens after the third immunization (Figure 2). VN antibodies to FIV_{Shi} in these cats developed after the fourth immunization, whereas VN antibodies to FIV_{Pet} were not detected over the course of the immunizations. Both of the Shi/FeT-1C vaccinated cats developed CTL responses to FIV_{Shi} only after the fourth immunization but did not develop CTL responses to FIV_{Pet}, even after the fourth immunization (Table 3).

Cats immunized with inactivated Pet/FL-4 cells developed antibodies to p25 after the second immunization (Figure 2) and to other viral antigens, including VN antibodies to FIV_{Pet}, after the second to third immunization (Table 4). The only CTL responses detected in cats immunized with Pet/FL-4 cells were to FIV_{Pet}. Overall, the dual subtype FIV vaccine induced more rapid and higher VN antibody titers and CTL responses to both FIV strains than the single-subtype vaccine. Sham immunized SPF cats did not develop viral antibodies, VN antibodies, or anti-FIV CTL responses.

Table 8. Cell tropism of FIV Isolates.

FIV (Subtype)	FIV Source	$TCID_{50}$[a] FeT-1C	PBMC	Alveolar Macrophage	Primary Microglia
Petaluma (A)	PBMC	10^4	10^4	10^2	ND
Petaluma (A)	FeT-1C[b]	10^4	10^4	10^1	ND
Petaluma (A)	FL-4[4]	10^4	10^4	10^1	ND
Dixon (A)	FeT-1C	10^4	10^3	10^1	ND
UK8 (A)	PBMC	10^2	10^3	10^3	ND
UK8 (A)	FeT-1C	10^3	10^3	10^3	ND
Bangston (B)	PBMC	10^3	10^3	10^3	10^2
Bangston (B)	FeT-1C[b]	10^3	10^3	10^3	10^2
Bangston (B)	FeT-J[b]	10^3	10^3	10^3	10^2
Shizuoka (D)	PBMC	10^2	10^3	<1	ND
Shizuoka (D)	FeT-1C[b]	10^3	10^3	<1	ND
Shizuoka (D)	FeT-J[b]	10^3	10^3	ND	ND

[a] - All virus inocula were adjusted to 120,000 cpm/ml of RT activity before titration on $5x10^5$ cells/ml of feline T cells (FeT-1C) or primary feline cells and the results represents the highest titer of the virus harvested over 21 days of culturing.

[b] - Same cells as the infected-cell vaccines.

It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and the scope of the appended claims.